

## **REMARKS**

Applicants, by the amendments presented above, have made a concerted effort to present claims which more clearly define over the prior art of record, and thus to place this case in condition for allowance.

5       Currently, claims 1-20 are pending. Claims 21-24 were cancelled without prejudice. Some of the claim dependencies have been amended.

### ***Claim Rejections - 35 U.S.C. §102(b)***

Claims 1, 5-9, 14 and 18-20 were rejected under 35 U.S.C. §102(b) as allegedly being clearly anticipated by United States Patent No. 4,048,993 to Dobritz. Claims 1-3 and 5-8 were rejected under 35 U.S.C. §102(b) as allegedly being clearly anticipated by United States Patent No. 5,042,500 to Norlien. Claims 1-3, 5-8, 21, 22 and 26 were rejected under 35 U.S.C. §102(b) as allegedly being clearly anticipated by United States Patent No. 5,233,996 to Coleman. Claims 1, 5, 7, 14 and 19 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by United States Patent No. 3,163,707 to Darling. Reconsideration and withdrawal of these rejections is requested.

Independent claims 1 and 19 have been amended to clarify that the “limb” is a “flexible” conduit with very thin walls and to clarify that the reinforcing member improves the axial stiffness of the conduit. Support for this can be found on page 15 (paragraph 1) of the specification as filed. In addition, independent claims 1 and 19 have been amended to include some of the limitations of originally filed claim 4 (and this limitation has been deleted from claim 4).

Independent claims 1 and 19 require that the limb for a breathing circuit be “a very thin walled conduit”. The term “very thin walled conduit” is defined under the heading Summary of the Invention as: “. . . a conduit where under the intended prevailing conditions the conduit would be subject to excessive axial compression . . .” The claimed invention is directed to solving a problem that has not existed in the field before because no prior art conduits have been constructed from such thin materials (i.e. less than 50 microns). Conduits of the prior art have had sufficiently thick walls such that when combined with traditional helical reinforcement, the axial stiffness (particularly compressive) of the conduit is adequate to withstand all but the most extreme loading situations.

The benefits of additional flexibility, light weight and improved breathability (when coupled with breathable materials) of very thin walled conduits comes at the expense of reduced axial stiffness of the conduit in both tension and compression. As described in the Summary of the Prior Art Section of the present patent application, very thin walls can lead to substantial internal volume changes under fluctuating breathing pressures. The claimed invention is directed to reinforcing a very thin walled conduit (with all the advantages that follow) to give adequate axial stiffness while maintaining a low bending stiffness and high flexibility of the conduit. It is consistent with the invention as described that the term “axial stiffness” include both tensile and compressive stiffness.

None of Dobritz, Norlien, Coleman and Darling disclose or suggest reinforcing for breathing conduits, nor do they disclose or suggest very thin walled conduits as clearly required by claim 1; neither Dobritz nor Darling disclose or suggest reinforcing for breathing conduits, nor do they disclose or suggest very thin walled conduits as clearly required by claim 19.

Applicant submits that one of ordinary skill in the art would not look to the Dobritz, Norlien, Coleman or Darling, nor would one of ordinary skill in the art be led to the construction of the claimed invention, even if they were aware of these documents because the cited prior art does not address reinforcement.

5           Applicant submits that when examining the prior art that does relate to reinforcing conduit, one of ordinary skill in the art would be taught to utilize more robust **helical** reinforcing. This type of reinforcing is adequate for thicker walled breathing conduits, but when applied to very thin walled conduits, the requisite axial stiffness can only be achieved by sacrificing weight and flexibility to unacceptable levels. In contrast, the claimed invention utilizes a novel reinforcing structure that provides adequate axial stiffness, while also providing adequate flexibility. In order to do so, the present invention teaches away from employing only traditional helical reinforcement which is bonded to the tubing along its length.

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While the above statements address a general argument relevant to the Examiner's rejections, the following addresses the Examiner's rejections more specifically.

15           Dobritz discloses a humidity exchanger which includes a gases pathway which follows a serpentine path through the exchanger (Figure 1). Claims 1 and 19 claim "a limb for a breathing circuit", and it is unclear whether the Examiner considers the exchanger 3 of Dobritz or the pathways 9, 10 of Dobritz, to be "a limb" which allegedly anticipates the claims.

If the Examiner considers the exchanger 3 to be a "limb", Applicant submits that there is no reinforcing member "along a non-tortuous path" as clearly required by claims 1 and 19. The serpentine gases pathways 9,10 are clearly excluded by the claim language. Further, the serpentine conduit is not a "reinforcing member which does not include a passageway large

enough for gases delivery to a patient” as required by amended claims 1 and 19. Applicant also notes that the exchanger 3, is not a “flexible conduit” nor are the walls “very thin” as required by amended claims 1 and 19.

If the Examiner considers the gases pathways 9, 10 to be a limb, Applicant submits that  
5 the barrier membrane does not fall within the term “reinforcing member” as required by claims 1 and 19. Applicant submits that the diffusion foil of Dobritz is so thin as to provide no practical enhancement of axial stiffness, and cannot therefore be described as “reinforcement” improving the axial stiffness of the conduit. It is clear that the object of the claimed invention is to provide improved axial stiffness is not met by the disclosure of Dobritz. Further, Dobritz does not  
10 disclose a very thin walled conduit as required by claims 1 and 19.

Norlien discloses a gas sample line with a sweep gas passing over the inner conduit.

Norlien does not disclose a very thin walled conduit as required by claim 1, nor does it disclose a limb for a breathing circuit as required. The outer jacket 18 of the Norlien device does not define a breathing gases pathway but rather carries a sweep gas from a pump (not shown).  
15 The jacket is disclosed as being of a material commonly used as medical tubing and the wall thickness distinguishes this device from claim 1 which requires a very thin wall.

Because of these differences, it is clear that Norlien does not anticipate claim 1, and it is noted that the device of Norlien does not suffer the problems to which the claimed invention is directed. Norlien does not disclose reinforcing a conduit, and a person of ordinary skill in the art would not be motivated by Norlien to consider the present problem, nor would they arrive at the  
20 presently claimed invention.

Similarly, Coleman does not disclose a very thin walled conduit, and it is unclear what the Examiner considers to be an “elongate reinforcing member lying freely within said very thin walled conduit”. Further, Coleman does not disclose reinforcement of a conduit and could not therefore lead a person of ordinary skill in the relevant art to the claimed invention.

5 Darling discloses a conduit with tensile strain limiting cords extending co-axially of the bore. These cords are sheathed in a compliant rubber tube. The objects of Darling make it clear that the conduit is provided with reinforcement against elongation under severe stress, strain and external force.

Darling document does not disclose a very thin walled conduit as claimed in claims 1 and  
10 19. It is also clear from the disclosure in Darling that the rubber tube provides no axial compressive reinforcement, and very little axial tensile reinforcement. The only significant reinforcement is provided by the cords inside the tube which limit *elongation* of the tube. The device of Darling does not provide any compressive axial reinforcement and is not capable of solving the problem to which the claimed invention is addressed. Therefore, the device of  
15 Darling does not improve the axial stiffness of the conduit as required by amended claims 1 and 19. Darling does not disclose a very thin walled tube nor does it teach reinforcement of such a tube to improve its axial stiffness (including compressive).

A person skilled in the relevant art when reading the description and claims of the present invention would understand that the “elongate reinforcing member” as claimed must provide not  
20 only tensile reinforcement, but also compressive reinforcement in order to “improve the axial stiffness”. Applicant submits that Darling does not anticipate claims 1 or 19, nor does it suggest the present invention.

Therefore, Applicant submits that claim 1 is not anticipated by, or rendered obvious by Dobritz, Norlien, Coleman or Darling; and that claim 19 is not anticipated by, or rendered obvious by Dobritz or Darling. Reconsideration and allowance of claims 1 and 19 is requested.

Claims 5-9, 14 and 18 are dependent upon claim 1 which Applicant submits is in  
5 condition for allowance. Therefore, Applicant submits that these claims are allowable.  
Reconsideration and allowance of same is requested.

#### ***Claim Rejections - 35 U.S.C. §103***

Claims 1, 3, 4 and 9-13 were rejected under 35 U.S.C. §103 as allegedly being  
10 unpatentable over United States Patent No. 4,838,258 to Dryden<sup>1</sup> in view of United States Patent No. 4,517,404 to Hughes. Reconsideration and withdrawal of these rejections is requested.

Independent claim 1 specifies “an elongate reinforcing member lying freely within said very thin walled conduit along a non-tortuous path from one end of said conduit to the other end of said conduit, and connected with said first connector and said second connector, such that said 15 reinforcing member substantially improves the axial stiffness of said conduit”. Neither Dryden nor Hughes discloses or suggests reinforcing of conduits by an elongate reinforcing member lying along a non-tortuous path. In fact, neither Dryden nor Hughes discloses or suggests

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<sup>1</sup>The Examiner did not cite the actual patent numbers in the Office Action. With regard to the rejection under 35 U.S.C. §103 of claims 1, 3, 4 and 9-13 over Dryden in view of Hughes, Linda Palomar, counsel for Applicant, spoke with the Examiner and he advised us that the applied Dryden reference is United States Patent No. 4,838,258, however, he also advised that if the numbers recited in the Office Action do not appear to correspond with United States Patent No. 4,838,258, that we should notify him of same for further comment.

reinforcing a conduit. In each case, the elongate member is taught for an unrelated reason such as fluid conveyance.

The Examiner suggests that Figure 4 of Dryden shows a member following a slightly tortuous path. However, Figure 4 does not actually show the path of the member between the end connectors at all, but merely the end positions. Figure 3 shows that the path is indeed tortuous, and thereby discloses a configuration that is outside of the claim. By its very shape the member of Dryden would be incapable of providing any substantial axial reinforcement as required by the claim, which is fundamental to the claimed invention.

Independent claim 1 also specifies “a very thin walled flexible conduit”. In Dryden and Hughes, the conduits are not very thin walled as required by claim 1. As discussed above, this means that the conduits in Dryden and Hughes do not suffer the problem to which the claimed invention is directed. Therefore, a person of ordinary skill in the relevant art would not be led to the method of the claimed invention by studying Dryden and/or Hughes which do not disclose or suggest reinforcing methods, and which do not relate to conduits of the claimed type.

Therefore, Applicant submits that claim 1 is not rendered obvious by Dryden in view of Hughes. Reconsideration and allowance of claim 1 is requested.

Claims 3, 4 and 9-13 are dependent upon claim 1 which Applicant submits is in condition for allowance. Therefore, Applicant submits that these claims are allowable. Reconsideration and allowance of same is requested.

Claims 2, 8, 15 and 16 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Darling. Claim 6 was rejected under 35 U.S.C. §103 as allegedly being unpatentable over Darling in view of United States Patent No. 4,874,925 to Dickenson. Claims

17 and 18 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Darling in view of United States Patent No. 2,943,644 to Moseley. These claims are dependent upon claim 1 which Applicant submits is in condition for allowance. Therefore, Applicant submits that these claims are allowable. Reconsideration and allowance of same is requested.

5 Claim 20 was rejected under 35 U.S.C. §103 as allegedly being unpatentable over Darling in view of United States Patent No. 2,943,644 to Moseley. Claim 20 is dependent upon claim 19 which Applicant submits is in condition for allowance. Therefore, Applicant submits that claim 20 is allowable. Reconsideration and allowance of same is requested.

10 ***Information Disclosure Statement***

Applicant apologizes for the duplication of prior art on the respective PTO-Forms 1449.

Applicant submits that the references the Examiner did not consider in the Information Disclosure Statements were timely submitted and should have been considered.

With regard to the Information Disclosure Statement submitted on December 5, 2003,  
15 Applicant encloses a copy of the stamped return postcard which indicates that all 71 references were received by the Patent Office. Therefore, WO 9718001 should have been considered. For the Examiner's convenience, Applicant encloses another copy of WO 9718001 as it appears that the original was lost in the Patent Office. With regard to the Perma Pure website information, the Examiner advised that no date was provided. Applicant submits that in this Information Disclosure Statement, Applicant stated that:

With regard to the one page printed from the Sympatex website (<http://www.permapure.com/104.html>) regarding the "Perma Pure Inc. New PD™-series gas dryers", Applicant submits that this document discloses an in-line gas drying product for industrial applications. The Perma Pure dryer element is a bundle of 0.03

inch diameter Nafion tubes housed within a tubular housing. A dry purge gas passes through the housing counterflow to the sample flow through the Nafion tubes. Applicant admits that this page was publicly available at least as early as May 9, 2000. Therefore, consideration of this document is requested.

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Therefore, Applicant submits that this document should have been considered. Consideration of same is requested.

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With regard to the Information Disclosure Statement submitted on December 10, 2003, Applicant encloses a copy of the stamped return postcard which indicates that all 17 references were received by the Patent Office. Therefore, EP 0557040 and JP 62236724 should have been considered. For the Examiner's convenience, Applicant encloses another copy of each of EP 0557040 and JP 62236724 as it appears that the originals were lost in the Patent Office. As previously indicated, JP62236724 is not in the English language. As advised in the Information Disclosure Statement:

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It is relevant because it discloses a three layer spirally wound conduit wherein the intermediate layer is a polyimide film having a coating of FEP while the inner and outer layers are metallic. After winding, the lengths of conduit are heated in a furnace until the outer surface of the FEP is molten and adheres to the outer layer. The inner layer is subsequently peeled away.

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Therefore, Applicant submits that these items of prior art should have been considered.

Consideration of same is requested.

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For the Examiner's convenience in indicating that these items have been considered, a new Form PTO-1449 is enclosed. Should the Examiner believe a fee is required for consideration of same, the United States Patent and Trademark Office is hereby authorized and requested to charge the fee to the deposit account of the undersigned firm, Account No. 20-1495.

A Petition for a Three-Month extension of time to extend the date for response up to and including June 20, 2006 is enclosed.

In view of the above Remarks, Applicants respectfully submit that the claims of the  
5 application are allowable over the rejections of the Examiner. Should the Examiner have any questions regarding this Amendment, the Examiner is invited to contact one of the undersigned attorneys at (312) 704-1890.

10 Respectfully submitted,

Dated: June 19, 2006

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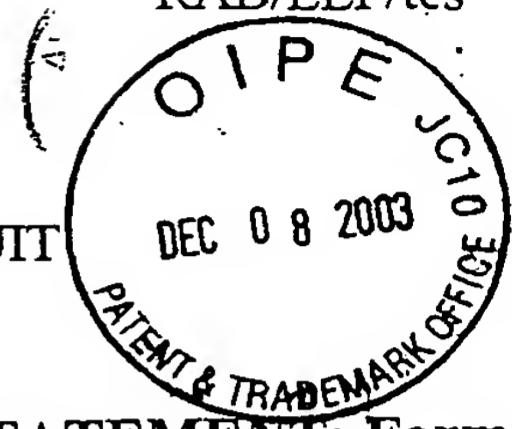
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Case 134  
1171/41357

December 5, 2003  
RAB/LLP/tes

Serial No.: 10/653,821  
Filed: September 3, 2003  
For: LIMB FOR A BREATHING CIRCUIT  
Applicant: GRAY et al.



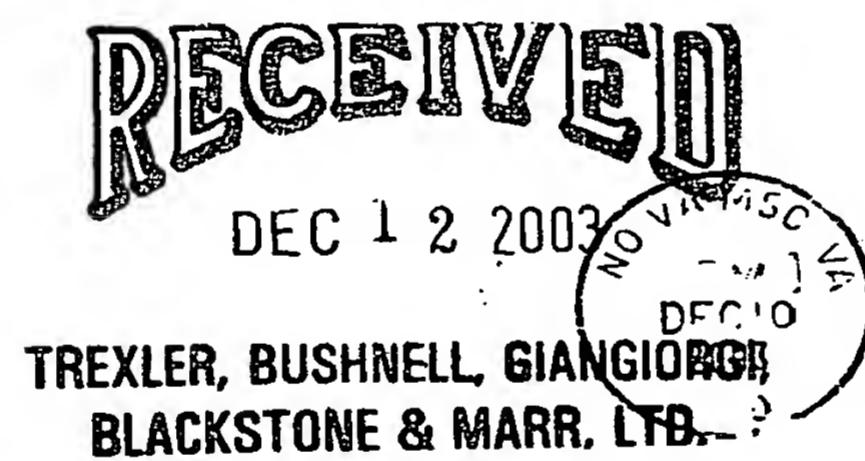
Enclosed: INFORMATION DISCLOSURE STATEMENT; Form PTO-1449; 71 cited references; Certificate of First Class Mailing, and this postcard.

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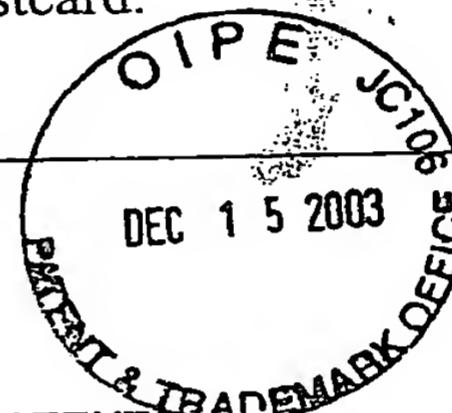
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Enclosed: **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT; Form PTO-1449; 17 cited references; Certificate of First Class Mailing, and this postcard.**

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